Drug Enforcement Administration

[Docket No. DEA-756]

Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cedarburg Pharmaceuticals has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on October 16, 2020, Cedarburg Pharmaceuticals 870 Badger Circle, Grafton, Wisconsin 53024, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Tetrahydrocannabinols	7370	I
3, 4-Methylenedioxymethamphetamine	7405	I

Dimethyltryptamine	7435	I
Psilocybin	7437	I
Methylphenidate	1724	II
Nabilone	7379	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Fentanyl	9801	II

The company plans to manufacture bulk active pharmaceutical ingredients (API) for distribution to its customers. In reference to the drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture as synthetic. No other activity for this drug code is authorized for this registration.

William T. McDermott,

Assistant Administrator.

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